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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/332,063

06/14/99

HOLMGREN

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3362-0101P

002292

HM12/1002

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EXAMINER

HARRIS, A

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

10/02/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/332,063

Applicant(s)

HOLMGREN ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-38 is/are pending in the application.
- 4a) Of the above claim(s) 26-29, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 30-34 and 38 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. Claims 1 and 3-38 are pending.

Claims 9-25 have been canceled.

Claims 34-38 have been added.

Claims 26-29, 36 and 37, drawn to non-elected inventions are withdrawn from examination.

Claims 1, 3-8, 30-35 and 38 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

3. Newly submitted claims 36 and 37 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims elected for examination are drawn to a product, an isolated human protein and not methods for treating and manufacturing compositions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36 and 37 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Maintained Grounds of Rejection

Claim Rejections - 35 U.S.C. § 112

4. The rejection of claims 1, 3-6 and 30-33 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicants assert that "...a 37 CFR §1.132 declaration certifying that the element, "wherein said protein or said peptide does not cleave plasminogen kringle" (i.e. it inherently lacks proteolytic activity) is an inherent property of the enzyme." This is found unpersuasive.

This extrinsic evidence attested by Dr. Holmsten is found not to be commensurate in scope with the claims. The claims reference kringle domains 1-4 and/or 5. The invention is directed to an isolate human protein having anti-angiogenic activity and is a receptor for the said domains. It is still not clear from the declaration if the ABP-1 protein of the invention is a receptor for kringle domains 1-4 or just kringle 5 or kringles 1-5. In light of these facts the rejection is maintained.

Claim Rejections - 35 U.S.C. § 102

5. The rejection of claim 7 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,916,572 (filed November 14, 1995) is maintained. Applicants' arguments are "...Reed has 5 contiguous amino acid with SEQ ID NO:2 is not sufficient to show that it also binds an N-terminal region of plasminogen." and the rejection is inapposite. This is found unpersuasive.

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Applicants have not provided substantial evidence that the amino acid residues of patent '572 would not bind. One of ordinary skill in the art would reasonably conclude that the amino acid residues of the patent also possess the same binding affinity to the N-terminal fragment of plasminogen and therefore it appears that the patent has a peptide that is identical to the amino acid residues to be implemented in the claimed invention. Since the Patent and Trademark Office does not have the facilities for examining and comparing the binding affinities of the patent's peptide and the peptide of the claim, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the amino acid residues in the claimed invention. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

New Grounds of Rejection

Claim Rejections - 35 U.S.C. § 102

6. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Petersen et al. (Journal of Biological Chemistry 205(11):6104-6111, 1990). Petersen et al. disclose fibrin, a human angiogenesis-associated protein capable of binding an N-terminal fragment of plasminogen, wherein the N-terminal fragment of plasminogen is constituted by the kringle domains 1 to 4 of plasminogen, the same as that claimed.

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Applicants argue in anticipation of this instant rejection that "...there is no published evidence that fibrin has anti-angiogenic activity. and "...do not believe that there has ever been a report that fibrin has any effect on angiogenesis." This is found unpersuasive.

Applicants state an opinion and have not based this argument on any scientific evidence of record. There is not evidence presented that is contrary to Petersen's protein not acting and sustaining the same properties as what is being claimed. One of ordinary skill in the art would reasonably conclude that the isolated human protein of Petersen would also possess the same properties of the protein claimed. Since the Patent and Trademark Office does not have the facilities for examining and comparing the activities of Petersen's protein and the protein of the claim, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the amino acid residues in the claimed invention. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Applicants should also take note of the Office Action mailed September 19, 2000 (Paper number 14) pages 6 and 7, paragraph 17.

Claim Rejections - 35 U.S.C. § 103

7. Claims 34 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable Petersen et al. (Journal of Biological Chemistry 205(11):6104-6111, 1990), in view of U.S. Patent # 5,679,350 (filed May 8, 1996). The teachings of Petersen have been presented above. Petersen does not teach the isolated human protein of claim 34 in composition form together with a pharmaceutically acceptable carrier.

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However, U.S. Patent # 5,679,350 teaches anti-angiogenesis proteins coupled with a carrier contained within a medicament, see abstract. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to produce anti-angiogenic proteins within a pharmaceutically acceptable carrier. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings of Petersen and U.S. Patent # '350 that such medicaments are useful and are targeted to patients with an angiogenesis-related disease or disorder such as cancer as suggested in the patent.

8. Claims 3-8, 31-33 and 35 are free of the art.

Allowable Subject Matter

9. Claims 8 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703)308-4310. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
October 1, 2001


SHEELA HUFF
PRIMARY EXAMINER